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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/469,738 12/21/99 CHANG

J 056301.P478

EXAMINER

QM12/1003
BLAKELY SOKOLOFF TAYLOR & ZAFMAN LLP
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HAYES, M
ART UNIT PAPER NUMBER

3763
DATE MAILED:

3
10/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/469,738

Applicant(s)

CHANG, JOSEPH J.

Examiner

Michael J Hayes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 16 recites the limitation "the porous member" in line 1. There is insufficient antecedent basis for this limitation in the claim.

4. Claim 16 is indefinite because it is not clear whether applicant is reciting that blood exits the porous member when it exits the catheter unit or whether blood exits the catheter on its path to the porous member.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

(f) he did not himself invent the subject matter sought to be patented.

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6. Claims 14 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by LUTHER (U. S. Patent No. 5,743,882). Luther discloses a catheter unit including a housing, needle, blunting member, and flash chamber. The blunting member axially moves within needle bore.

7. Claims 14, 15, and 17 are rejected under 35 U.S.C. 102(e) or 102(f) as being anticipated by SOLOMON et al. (U. S. Patent No. 6,210,379 B1). Solomon discloses a catheter unit including needle, blunting member, flash chamber, and removable porous plug.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over LUTHER ('882) as applied to claim 14 above, and further in view of LUTHER (U. S. Patent No. 5,120,317). Luther ('882) discloses the claimed invention except for a removable porous plug with porosity 35-55% that allows fluid to exit the catheter after thirty seconds. Luther ('317) discloses a removable porous plug 16 to allow air to escape a flash chamber and to allow a syringe to connect to the flash chamber. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the removable porous plug as taught by Luther ('317) in the catheter unit of Luther ('882) in order to allow blood collection in the flash chamber and removal or supply of fluid from or to the chamber. Luther does not disclose a porosity of 35-

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55% or fluid exiting after 30 seconds. It would have been obvious to select a plug within this porosity range in order to vent air at a desired rate to tailor the blood accumulation in the flash chamber.

10. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over SOLOMON as applied to claim 14 above, and further in view of CHANG (U. S. Patent No. 4,917,671).

Solomon discloses the claimed invention except for 35-55% porosity and fluid exit after thirty seconds. Chang teaches using 35-55% porosity to permit air permeability. It is inherent that 35-55% porosity will permit fluid exit after thirty seconds. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the porosity as taught by Chang in the invention of SOLOMON in order to rapidly vent air from the flash chamber

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 14, 15, and 17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-15, 22 of U.S. Patent No. 6,210,379

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B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because each recite a blunting member, needle, flash chamber and porous plug.

13. Claim 16 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-15, 22 of U.S. Patent No. 6,210,379 in view of CHANG. Patent ('379) discloses the claimed invention except for 35-55% porosity and fluid exit after thirty seconds. Chang teaches using 35-55% porosity to permit air permeability. It is inherent that 35-55% porosity will permit fluid exit after thirty seconds. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the porosity as taught by Chang in the invention of Patent '379 in order to rapidly vent air from the flash chamber.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. SAHI et al. (U. S. Patent No. 4,828,547) shows a blunting needle assembly.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Seidel, can be contacted at (703) 308-5115. The fax number for submitting official papers is (703) 872-9302. The fax number for submitting after final papers is (703) 872-9303.



Michael J. Hayes
29 September 2001